

EPA JACKET 69361-42

Material Sent for Data Extraction

Reg. # 69361-42

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 9-3-13

☐ Notification Dated _____

☒ New CSF(s) Dated 8-21-13

☐ Other: _____

☒ Decision #: 477460

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carmen Rodia

Phone: (703) 306-0327 Division: RD/IB

Date: 9-3-13



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7504P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460-0001

EPA Reg. Number:

69361-42

Date of Issuance:

SEP 3 2013

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Repar Fipronil Technical

Name and Address of Registrant (include ZIP Code):

Repar Corporation
P.O. Box 4321
Silver Spring, MD 20914

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.

(continued on page 2)

Signature of Approving Official:

Refer to Page #2.

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7504P)

Date:

SEP 3 2013

2. Make the following change(s) to the subject label:

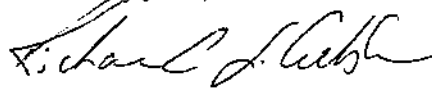
- a. Change the product registration number to "EPA Reg. No. 69361-42"
- b. Make the following label revisions:

General Comment(s):

1. Submit and/or cite all data required for reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data. See the data requirements in the referenced Data Call-In (DCI) which can be found in the fipronil docket at <http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OPP-2011-0448-0040>
2. You have ninety (90) days from the date of this Notice of Registration to provide a response on how you will fulfill the data requirements listed in the DCI referenced in item #1 above by the deadlines described in the DCI.
3. You must submit two (2) copies of the revised final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

Copies of your label stamped "Accepted with Comments" as well as the OPP similarity clinic reviews completed for this product are enclosed for your records. If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated September 3, 2013*
 OPP Similar Clinic Review #1, dated April 25, 2013
 OPP Similar Clinic Review #2, dated August 26, 2013

069361-00042 D477460

Repar Corporation [Company Logo]
REPAR FIPRONIL TECHNICAL
 FOR MANUFACTURING PURPOSES ONLY

ACCEPTED
 With COMMENTS
 In EPA Letter Dated: *September 3, 2013*
 Under the Federal Insecticide, Fungicide
 and Rodenticide Act, As amended, for the
 pesticide Registered under EPA Reg. No:
69361-42

Active Ingredient:

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1,R,S)-
 (trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile 98.0%
 Other Ingredients: 2.0%
Total **100.0%**

KEEP OUT OF REACH OF CHILDREN

WARNING

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
 (If you do not understand this label, find someone to explain it to you).

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Avoid alcohol. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call: 1-(866)-359-5660	
Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.	

NET CONTENTS:

EPA Reg. No.: 69361-UE
 EPA Est. No.:

Repar Corporation
 P. O. Box 4321 · Silver Spring, MD 20914

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING. May be fatal if swallowed. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and, in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, estuarine and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product. Only for formulation into insecticide or rodenticide products.

For Manufacture Use only into insecticide products for the following uses*:

- Residential Indoor: (Companion animals, crack and crevice baits, and bait stations).
- Indoor non-food (commercial, industrial, and institutional facilities, modes of transportation), crack and crevice baits, and bait stations.
- Termiticides: (pre and post construction soil application, indoor sub-slab).
- Terrestrial non-food: (golf courses, sod farms, commercial lawns, and perimeter treatment around commercial buildings).
- Residential outdoor: (lawns, perimeter treatment around buildings and ornamentals).

This product may be used to formulate products for specific use(s) not listed on the Master Product (MP) Label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration for their end-use product(s).

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

- This product is not for formulation into end-use product for use in or on food/feed areas, including food handling establishments (except for crack and crevice, and bait station products) or in/on food/feed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store upright in original container in a well-ventilated area that is inaccessible to children, animals, fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal:

Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by the State and Local authorities. **Fiber Drums with Liners:** Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of liner in a sanitary landfill, or by other procedures approved by State and Local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose only when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. This is the only warranty made on this product. To the extent of applicable law seller expressly disclaims any implied warranties of merchantability or fitness for any purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. To the extent of applicable law in no case shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. The Buyer shall assume all such risks. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.



Decision Seq: 477460	Action Code: R300, NEW PRODUCT, OR SIMILAR COMBINATION PRODUCT (...)		Decision Status	
FFS Start Date: 01-May-2013	Tentative Ind: No	Start/Stop Clock	FGPA Clock	Tracking
Due Date: 03-Sep-2013	75-Day Due Date:	Days Elapsed:		Create Resubmission
OPP Target Due Date:	21-Day Due Date: 01-May-2013	FFS Original Decision:		FFS Letters
Negotiated Due Date:	45-Day Due Date: 17-Jun-2013			Waiver Documentation
Registrant:	Predecisional Due Date: 20-Aug-2013			Action Code History
Response Due Date:				Secondary Decision
Current Status: PENDING (03-Sep-2013)				
75 Day Letters	45/90 Day Screen	Primary Decisions		
FFS Negotiated Due Dates	OPP Target Due Date	Decision Comments	Payment	Unmatched Payments
Decision Ownership	Receipts	Data Package	Reduced Risk	Meetings & Milestones
FFS Information				
Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Respor ^
S: 940583	Rodia, Carmen	69361-UE	03-Sep-2013	PENDING
Submission of a further updated proposed label.				
S: 939989	Rodia, Carmen	69361-UE	03-Sep-2013	SUPERSEDED BY NEW RECEIPT
Submission of revised basic CSF, label, and administrative materials related to change of active name of proposed product.				
S: 933519	Rodia, Carmen	69361-UE	03-Sep-2013	SUPERSEDED BY NEW RECEIPT
Initial application 100% repack.				

Viewing Record 1 of 1

Rodia, Carmen

From: Madhu Mandava [Madhu@Mandava.com]
Sent: Tuesday, September 03, 2013 1:59 PM
To: Rodia, Carmen
Cc: Gebken, Richard
Subject: RE: Preliminary Label Review Comments for EPA File Symbol 69361-UE (Repar Fipronil Technical)
Attachments: 69361-UE 20130830c Fipronil Repar (3).pdf

Dear Carmen,

Attached is the revised label per the Agency's comments. Looking forward to receiving the EPA Notice of Registration.

Best Regards,

Madhu Mandava
Vice President
Mandava Associates, LLC
6860 N. Dallas Parkway
Suite 200
Plano, TX 75024
Tel: (972) 265-7924
Fax: (202) 223-0141
www.mandava.com

From: Rodia, Carmen [mailto:Rodia.Carmen@epa.gov]
Sent: Thursday, August 29, 2013 11:51 AM
To: Madhu Mandava
Cc: Gebken, Richard; Rodia, Carmen
Subject: Preliminary Label Review Comments for EPA File Symbol 69361-UE (Repar Fipronil Technical)

Madhu, in anticipation of stamping a "clean label" in support of the pending application for EPA File Symbol 69361-EU (Repar Fipronil Technical), I have the following preliminary label review comments that will need to be incorporated into a final amended proposed label:

First Aid Statements section comment(s), bottom of page 1 of 3:

1. To facilitate inclusion of required label language from the OPP similarity clinic reviews completed in support of the subject product, you must delete the proposed **"IF IN EYES:"** subsection.

Precautionary Statements, Hazards to Humans and Domestic Animals subsection comment(s), top of page 2 of 3:

2. To facilitate inclusion of required label language from the OPP similarity clinic reviews completed in support of the subject product, you must revise this subsection to read "May be fatal if swallowed. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse."

Directions for Use section comment(s), bottom of page 2 of 3:

3. To facilitate inclusion of required label language from the RED for fipronil, within the last text statement at the bottom of page 2 of 3, you must replace the misspelled word "cre3vice" with the word "crevice."

Storage and Disposal Statement section comment(s), top of page 3 of 3:

4. To facilitate inclusion of required label language from PR Notice 2007-4 and/or the Agency's Label Review Manual, you must make the following changes:
- Revise the existing 1st sentence within the "**Pesticide Storage:**" subsection to read "Store upright in original container in a well-ventilated area that is inaccessible to children, animals, fertilizer, feed and foodstuffs."
 - Revise the existing 1st sentence within the "**Container Disposal:**" subsection to read "Do not reuse or refill this container."
 - Revise the existing 6th sentence within the "**Container Disposal:**" subsection to read "Then dispose of liner in a sanitary landfill, or by other procedures approved by State and Local authorities."

As such, you must submit a final amended proposed label which incorporates all of the above preliminary label review comments. If you have any questions, please call me directly. Once the label has been updated, please e-mail it to me for use in registering this new product. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

Repar Corporation [Company Logo]
REPAR FIPRONIL TECHNICAL
 FOR MANUFACTURING PURPOSES ONLY

Active Ingredient:

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1,R,S)-
 (trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile 98.0%
 Other Ingredients: 2.0%
Total **100.0%**

KEEP OUT OF REACH OF CHILDREN
WARNING

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
 (If you do not understand this label, find someone to explain it to you).

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Avoid alcohol. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call: 1-(866)-359-5660	
Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.	

NET CONTENTS:

EPA Reg. No.: 69361-UE
 EPA Est. No.:

Repar Corporation
 P. O. Box 4321 · Silver Spring, MD 20914

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING. May be fatal if swallowed. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and, in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, estuarine and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store upright in original container in a well-ventilated area that is inaccessible to children, animals, fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

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Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose only when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. This is the only warranty made on this product. To the extent of applicable law seller expressly disclaims any implied warranties of merchantability or fitness for any purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. To the extent of applicable law in no case shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. The Buyer shall assume all such risks. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Rodia, Carmen

From: Rodia, Carmen
Sent: Thursday, August 29, 2013 12:51 PM
To: Madhu Mandava
Cc: Gebken, Richard; Rodia, Carmen
Subject: Preliminary Label Review Comments for EPA File Symbol 69361-UE (Repar Fipronil Technical)

Madhu, in anticipation of stamping a "clean label" in support of the pending application for EPA File Symbol 69361-EU (Repar Fipronil Technical), I have the following preliminary label review comments that will need to be incorporated into a final amended proposed label:

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Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Insecticide Branch
1200 Pennsylvania Avenue, NW (7504P)
Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

DATE August 26 2013

MEMORANDUM

Subject: EPA File Symbol/Reg. No.: 69361-UE

Product Name: Fipronil Technical
DP Barcode: 414244
Decision No.: D477460
Action Code: R300
PC Code: 129121 Fipronil (98%)

From: John C. Redden, M.S.
Technical Review Branch (TRB)
Registration Division (7505P)

JCR E.McA

To: Carmen Rodia PM10
Insecticide Branch
Registration Division (7505P)

Applicant: Repar Corporation
P.O. Box 4321
Silver Spring, MD 20914

<u>Active Ingredient</u>	<u>% by weight</u>
Fipronil.....	98.0%
Inert Ingredients.....	<u>2.0%</u>
	100.0%

PC CODE/ Reg. No./File Symbol:

OPP Similarity Clinic

EPA File Symbol No. 69361-UE is claiming toxicity similarity to EPA Reg. No. [REDACTED]. It is also stated that 69361-UE is a 100% repack of [REDACTED]. We used the following document, [REDACTED] for the acute toxicity profile. We determined that the two products are substantially similar. [REDACTED]

[REDACTED]

Tox Profile:

PC CODE/ Reg. No./File Symbol:





Decision Seq: 477460 Action Code: R300, NEW PRODUCT, OR SIMILAR COMBINATION PRODUCT (...)

FFS Start Date: 01-May-2013 Tentative Ind: No Start/Stop Clock: FQPA Clock:

Due Date: 03-Sep-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 01-May-2013 FFS Original Decision: ...

Negotiated Due Date: 45-Day Due Date: 17-Jun-2013

Registrant: iel Prediscisional Due Date: 20-Aug-2013

Response Due Date:

Decision Status
Tracking
Create Resubmission
FFS Letters
Waiver Documentation
Action Code History
Secondary Decision

Current Status: PENDING (21-Aug-2013)

☒ 75 Day Letters
 ☒ 45/90 Day Screen
 ☐ Primary Decisions

☒ FFS Negotiated Due Dates
 ☒ OPP Target Due Date
 ☐ Decision Comments
 ☐ Payment
 ☐ Unmatched Payments

☒ Decision Ownership
 ☒ Receipts
 ☐ Data Package
 ☐ Reduced Risk
 ☐ Meetings & Milestones
 ☐ FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 939989	Rodla, Carmen	... 69361-UE	03-Sep-2013	PENDING
Submission of revised basic CSF, label, and administrative materials related to change of active name of proposed product.				
S: 933519	Rodla, Carmen	... 69361-UE	03-Sep-2013	SUPERSEDED BY NEW RECEIPT
Initial application 100% repack.				

Rodia, Carmen

From: Madhu Mandava [Madhu@Mandava.com]
Sent: Wednesday, August 21, 2013 3:50 PM
To: Rodia, Carmen
Subject: FW: Repar Fipronil Technical--69361-UE Submission
Attachments: Fipronil 8570-1 APP Me-Too registration--submission b (8-21-13).pdf; Fipronil formulator's exemption--submission b (8-21-13).pdf; New CSF-- Fipronil Tech (8-21-13).pdf; 69361-UE.20130821b.Fipronil.Repar.PDF

Dear Carmen,

On behalf of Repar Corporation, attached, please find the submission of revised information to support the name change to "Repar Fipronil Technical", as per your voice mail message request received yesterday, Tuesday, August 20, 2013.

Please let us know if you require additional information. We look forward to receiving the approved EPA Product Registration this week. If possible, please e-mail a copy of the EPA acceptance.

Best Regards,
Madhu

Madhu Mandava
Vice-President
Mandava Associates, LLC
6860 N Dallas Parkway
Suite 200
Plano, TX 75024
Tel: (972) 265-7924
Fax: (972) 265-7942
www.mandava.com

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From: Adam Matzer
Sent: Wednesday, August 21, 2013 11:34 AM
To: Madhu Mandava
Subject: Repar Fipronil Technical--69361-UE Submission

See attached.


Adam Matzer
Mandava Associates, LLC
6860 N. Dallas Parkway
Suite 200
Plano, TX 75024
Tel: (972) 265-7924
Fax: (972) 265-7942
AMatzer@mandava.com

Please read instructions on reverse b. completing form.		Form Approved, OMB 370-0080	Print Form
 United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 69361-UE		2. EPA Product Manager Richard Gebken	
4. Company/Product (Name) Repar Fipronil Technical		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Repar Corporation P. O. Box 4321 Silver Spring, MD 20914 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. [REDACTED] Product Name [REDACTED]	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input checked="" type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) New Product; Me-Too Registration; Fast Track; PRIA Category: R300, CR No. 44(Receipt Attached) submitted fee: \$358.50; Small Business Fee Waiver Exemption Please send all correspondence to Mandava Associates, L.L.C, 6860 N. Dallas Pkwy, Suite 200, Plano, TX 75024 Attn: Madhu Mandava E-mail: madhu@mandava.com			
Section - III			
1. Material This Product Will Be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 kg, 55 kg	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Madhu Mandava		Title Agent for Repar Corp.	Telephone No. (Include Area Code) 972-265-7924
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Repar Corporation	
4. Typed Name Madhu Mandava		5. Date August 21, 2013	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (original)

Yellow - Applicant Copy

Form Approved: OMB 370-0080, Approval Expires 5-31-99. United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement (40 CFR 152.85)		
Applicant's Name and Address Repar Corporation P. O. Box 4321 Silver Spring, MD 20914	EPA File Symbol/Registration Number 69361-UE Product Name Repar Fipronil Technical Date of Confidential Statement of Formula (EPA Form 8570-4) August 21, 2013	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1R,S)-(trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.		
(3) Indicate by checking (A) or (B) below which paragraph applies:		
<input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).		
OR		
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.		
(4) The following active ingredients in this product qualify for the formulator's exemption.		
Source		
Active Ingredient	Product Name	Registration Number
Fipronil	[REDACTED]	[REDACTED]
Signature 	Name and Title Madhu Mandava Agent for Repar Corporation	Date 08/21/2013

EPA Form 8570-27 (Rev. 8-95) White - EPA copy
 Yellow - Applicant copy

U.S. GPO: 1995-388-820/20413

Repar Corporation [Company Logo]
REPAR FIPRONIL TECHNICAL
 FOR MANUFACTURING PURPOSES ONLY

Active Ingredient:

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile 98.0%
 Other Ingredients: 2.0%
Total **100.0%**

KEEP OUT OF REACH OF CHILDREN

WARNING

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
 (If you do not understand this label, find someone to explain it to you).

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Avoid alcohol. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses if present, after the first 5 minutes, and then continue rinsing. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call: 1-(866)-359-5660	
Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.	

NET CONTENTS:

EPA Reg. No.: 69361-UE

EPA Est. No.:

Repar Corporation
 P. O. Box 4321 · Silver Spring, MD 20914

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING. May be fatal if swallowed, absorbed through the skin or inhaled. Causes substantial but temporary eye injury. Do not get in eye, on skin, or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Wear protective clothing and rubber gloves. Remove contaminated clothing and wash clothing before reuse. Do not breathe dust. Wear a dust/mist filtering respirator with any N, R, P or HE filter.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and, in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, estuarine and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product. Only for formulation into insecticide or rodenticide products.

For Manufacture Use only into insecticide products for the following uses*:

- Residential Indoor: (Companion animals, crack and crevice baits, and bait stations).
- Indoor non-food (commercial, industrial, and institutional facilities, modes of transportation), crack and crevice baits, and bait stations.
- Termiticides: (pre and post construction soil application, indoor sub-slab).
- Terrestrial non-food: (golf courses, sod farms, commercial lawns, and perimeter treatment around commercial buildings).
- Residential outdoor: (lawns, perimeter treatment around buildings and ornamentals).

This product may be used to formulate products for specific use(s) not listed on the Master Product (MP) Label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration for their end-use product(s).

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

- This product is not for formulation into end-use product for use in or on food/feed areas, including food handling establishments (except for crack and crevice, and bait station products) or in/on food/feed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal:

Nonrefillable Containers – Metal: Do not use or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by the State and Local authorities. **Fiber Drums with Liners:** Do not use or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of liner in a sanitary landfill, or by incineration, if allowed by State and Local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose only when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. This is the only warranty made on this product. To the extent of applicable law seller expressly disclaims any implied warranties of merchantability or fitness for any purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. To the extent of applicable law in no case shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. The Buyer shall assume all such risks. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Decision Information for 69361-UE



Initial a:		Decision Seq: 477460		Action Code: R300, NEW PRODUCT, OR SIMILAR COMBINATION PRODUCT (...)		Decision Status	
FFS Start Date: 01-May-2013		Tentative Ind: No		Start/Stop Clock:		Tracking	
Due Date: 03-Sep-2013		75-Day Due Date:		Days Elapsed:		Create Resubmission	
OPP Target Due Date:		21-Day Due Date: 01-May-2013		FFS Original Decision: ...		FFS Letters	
Negotiated Due Date:		45-Day Due Date: 17-Jun-2013				Waiver Documentation	
Registrant:		Predecisional Due Date: 20-Aug-2013				Action Code History	
Response Due Date:						Secondary Decision	
Viewing: Current Status: PENDING (11-Apr-2013)							
<input checked="" type="checkbox"/> 75 Day Letters <input checked="" type="checkbox"/> 45/90 Day Screen Primary Decisions <input checked="" type="checkbox"/> FFS Negotiated Due Dates <input checked="" type="checkbox"/> OPP Target Due Date <input checked="" type="checkbox"/> Decision Comments <input checked="" type="checkbox"/> Payment <input checked="" type="checkbox"/> Unmatched Payments <input checked="" type="checkbox"/> Decision Ownership <input checked="" type="checkbox"/> Receipts <input checked="" type="checkbox"/> Data Package <input checked="" type="checkbox"/> Reduced Risk <input checked="" type="checkbox"/> Meetings & Milestones <input checked="" type="checkbox"/> FFS Information							
Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response			
S: 933519	Rodra, Carmen	... 69361-UE	03-Sep-2013	PENDING			
Initial application 100% repack.							
<div style="text-align: center;"> </div>							

Viewing: Record 1 of 1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

DATE April 25, 2013

MEMORANDUM

Subject: EPA File Symbol/Reg. No.: 69361-UE

Product Name: Fipronil Technical
DP Barcode: 411227
Decision No.: D477460
Action Code: R300
PC Code: 129121 Fipronil (98%)

From: John C. Redden, M.S. *JCR*
Technical Review Branch (TRB) *HH*
Registration Division (7505P)

Through: OPP Similarity Clinic
Registration Division (7505P)

To: PM10
Insecticide Branch
Registration Division (7505P)

Applicant: Repar Corporation
P.O. Box 4321
Silver Spring, MD 20914

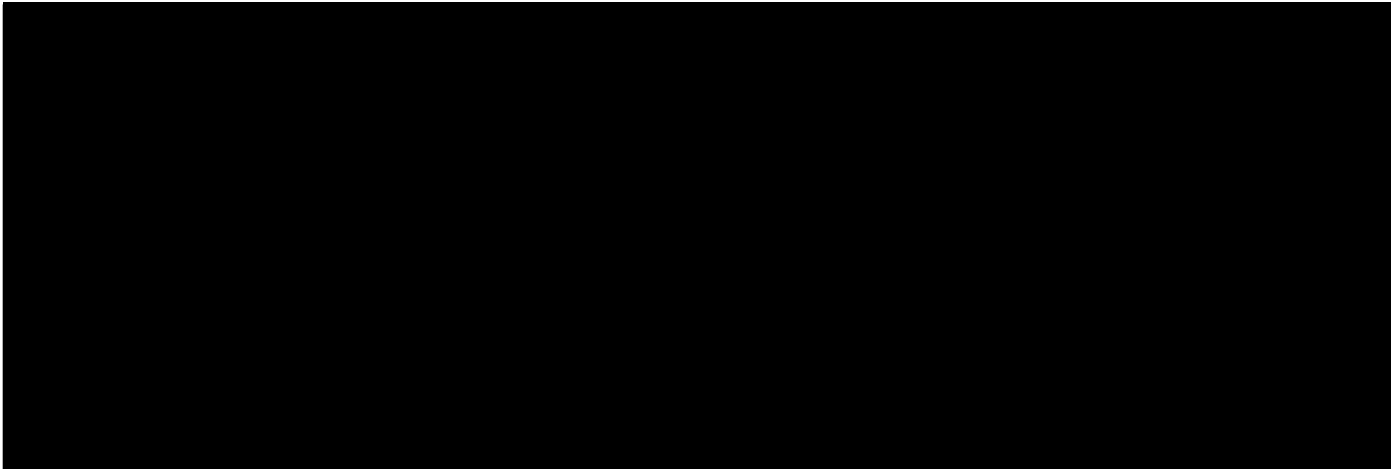
<u>Active Ingredient</u>	<u>% by weight</u>
Fipronil.....	98.0%
Inert Ingredients.....	<u>2.0%</u>
	100.0%

PC CODE/ Reg. No./File Symbol:

OPP Similarity Clinic

EPA File Symbol No. 69361-UE is claiming toxicity similarity to EPA Reg. No. [REDACTED]
It is also stated that 69361-UE is a 100% repack of [REDACTED] We used the following document, [REDACTED] for the acute toxicity profile. We determined that the two products are substantially similar.

Tox Profile:



PRODUCT ID #: 069361-00042

PRODUCT NAME:

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER POISON ☠

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Child Resistant Packaging Required.

Fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Avoid breathing spray mist. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Acute Oral Toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: John Redden on 04/25/2013

Last Updated by: John Redden on 04/25/2013

NEW APPLICATIONS



DATE: APR 10 2013

FILE REG NUMBER: 69361-UE

FEP (OPPIN ENTRY) LV APR 11 2013

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

SIG: _____

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

ASSIGN TO PM: AD ✓ **RD** 10 **BPPD** _____

_____ JACKET TO SHELF (DATA)

Similarity Clinic Screen Completed

Date: 4/22/13

Jacket #: 69361-UE

Actions Done:

Acute Toxicity Review: COMPLETED - IN JACKET

Acute Toxicity Language for Label: IN REVIEW

Product Chemistry Review: 100% REPACK OF



Transfer This Jacket To:

PM 10, RICHARD GERBEN

21-Day Screen Completed by
Contractor

21-Day Expires on 5/1/13

Jacket # 69361-UE

MRID# n/a

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schaible

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4/10/13
 Experts In-Processing Signature: MP Date 4/12/13 Fee Paid: Yes ☐
 Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>69361-UE</u>		EPA Receipt Date: <u>4/10/13</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	<div style="display: flex; justify-content: space-around;"> yes no </div> <div style="text-align: center; padding: 5px;">X</div>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X	
	Certificate and data matrix consistent				
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<div style="display: flex; justify-content: space-around;"> yes no </div>			
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)		X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X	
5	a) Selective Method (Fee category experts use)	<div style="display: flex; justify-content: space-around;"> yes no </div>			
	b) Cite-All (Fee category experts use)	<div style="display: flex; justify-content: space-around;"> yes no </div>			
	c) Applicant owns all data (Fee category experts use)	<div style="display: flex; justify-content: space-around;"> yes no </div>			
6	5 Copies of Label (<u>Electronic labels on CD</u> are encouraged and guidance is available)		X		
7	Is the data package consistent with PR Notice 86-5				X
8	Notice of Filing included with petitions				X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			x
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

~~100%~~ 100% repack, no inerts to review

Jack et Rag

FG

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 11, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-477460
EPA File Symbol or Registration Number: 69361-UE
Product Name: FIPRONIL TECHNICAL
EPA Receipt Date: 10-Apr-2013
EPA Company Number: 69361
Company Name: REPAR CORP

REPAR CORP
PO BOX 4321
SILVER SPRING, MD 20914

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Teresa Downs*
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{933519;~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75%

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 10

Receipt No.

S-

933519

EPA File Symbol/Reg. No.

69361-UE

Pin-Punch Date:

4/10/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300 (W)

Amount Due: \$ 1434⁰⁰

100% Repack

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *[Signature]*

Date: 4/11/13

Remarks:

sim clinic - needs tox profile

Receipt for Section 3

S: 933519

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 69361 REPAR CORP

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 69361-UE Product Name: FIPRONIL TECHNICAL

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 06-Apr-2013

ic

OPP Rec'd Date: 10-Apr-2013

ic

Front End Date: 11-Apr-2013

ic

Risk Manager Send Date:

ic

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New product me-too registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

CSF

Paper Label

View/Edit

Product ingredient source information may be entitled to confidential treatment

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.**Your transaction has been successfully completed.****Pay.gov Tracking Information****Application Name:** PRIA Service Fees**Pay.gov Tracking ID:** 25A9FBS3**Agency Tracking ID:** 74433671044**Transaction Date and Time:** 04/09/2013 21:47 EDT**Payment Summary****Address Information****Account Holder** Madhu
Name: Mandava
15404 Tindlay**Billing Address:** Street**Billing Address**

2:

City: Silver Spring**State / Province:** MD**Zip / Postal****Code:** 20905**Country:** USA**Account Information****Card Type:** American**Card Type:** Express**Card Number:** *****2011**Decision****Number:****Registration****Number:****Repar****Company Name:** Corporation**Company****Number:** 69361**Action Code:** R300**Payment Information****Payment Amount:** \$358.50**Transaction Date** 04/09/2013
and Time: 21:47 EDT

Please read instructions on reverse before

ing form.

Form Approv

AB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69361	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fipronil Technical	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Repar Corporation P. O. Box 4321 Silver Spring, MD 20914 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. [REDACTED] Product Name [REDACTED]	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New Product; Me-Too Registration; Fast Track: PRIA Category: R300, CR No. 44(Receipt Attached)
submitted fee: \$358.50; Small Business Fee Waiver Exemption
Please send all correspondence to Mandava Associates, L.L.C, 6860 N. Dallas Pkwy, Suite 200, Plano, TX 75024 Attn: Madhu Mandava
E-mail: madhu@mandava.com

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 kg, 55 kg	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Madhu Mandava	Title Agent for Repar Corp.	Telephone No. (Include Area Code) 972-235-7924
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Repar Corporation	
4. Typed Name Madhu Mandava	5. Date March 6, 2013	

MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

6860 N Dallas Parkway, Suite 200, Plano, TX 75024

Telephone: (972) 265-7924 / Fax: (202)-223-0141 / E-MAIL: Madhu@Mandava.com / www.Mandava.com

Via FEDEX:

March 6, 2013

Document Processing Desk (WAIVER)
Insecticide Branch
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Richard Gebken
Product Manager (10)

Subject: Repar Corporation - EPA Number 69361
APPLICATION FOR NEW PRODUCT—"ME-TOO" FAST TRACK R300
Fipronil Technical; Small Business Fee Waiver Exemption,
PRIA EPA Fee Category No.R300, CR No. 44

Dear Mr. Gebken,

On behalf of Repar Corporation, we are submitting a "Me-Too" Registration Application for Fipronil Technical. This registration application qualifies for an expedited review (Fast Track) as it is identical or substantially similar in composition, use, and labeling to [REDACTED]; EPA Reg. No. [REDACTED]

Enclosed, please find the following materials in support of the application for registration of Fipronil Technical:

- 1) Application for Pesticide Registration (EPA Form 8570-1)
- 2) Copy of EPA Payment of PRIA Fee
- 3) Copy of Small Business Fee Waiver Exemption Request
- 4) Formulator's Exemption Statement (EPA Form 8570-27)
- 5) Confidential Statement of Formula (EPA Form 8570-4)
- 6) Five (5) Copies of Draft Labeling

Please send to my attention the EPA Registration Notice and Stamped Approved Labels at the address listed below. We look forward to a quick approval of this application.

If you have any questions regarding this submission, please contact me at (972) 265-7924.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "M. Mandava", followed by a horizontal line.

Madhu Mandava
Mandava Associates, LLC
Agent for Repar Corporation
Phone: (972) 265-7924
E-MAIL: Madhu@Mandava.com

United States



Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Repar Corporation
P. O. Box 4321
Silver Spring, MD 20914

EPA File Symbol/Registration Number

69361-

Product Name

Fipronil Technical

Date of Confidential Statement of Formula (EPA Form 8570-4)

March 6, 2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1R,S)-(trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:


☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Fipronil	[REDACTED]	[REDACTED]
<div> <div>Signature </div> <div>Name and Title Madhu Mandava Agent for Repar Corporation</div> <div>Date 03/06/2013</div> </div>		

Repar Corporation [Company Logo]

FIPRONIL TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

Active Ingredient:

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl) phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile 98.0%

Other Ingredients: 2.0%

Total **100.0%**

KEEP OUT OF REACH OF CHILDREN

WARNING

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand this label, find someone to explain it to you).

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Avoid alcohol.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses if present, after the first 5 minutes, and then continue rinsing.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call: 1-(866)-359-5660	
Note to Physician: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.	

NET CONTENTS:

EPA Reg. No.:

EPA Est. No.:

Repar Corporation

P. O. Box 4321 · Silver Spring, MD 20914

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING. May be fatal if swallowed, absorbed through the skin or inhaled. Causes substantial but temporary eye injury. Do not get in eye, on skin, or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Wear protective clothing and rubber gloves. Remove contaminated clothing and wash clothing before reuse. Do not breathe dust. Wear a dust/mist filtering respirator with any N, R, P or HE filter.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and, in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, estuarine and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product. Only for formulation into insecticide or rodenticide products.

For Manufacture Use only into insecticide products for the following uses*:

- Residential Indoor: (Companion animals, crack and crevice baits, and bait stations).
- Indoor non-food (commercial, industrial, and institutional facilities, modes of transportation), crack and crevice baits, and bait stations.
- Termiticides: (pre and post construction soil application, indoor sub-slab).
- Terrestrial non-food: (golf courses, sod farms, commercial lawns, and perimeter treatment around commercial buildings).
- Residential outdoor: (lawns, perimeter treatment around buildings and ornamentals).

This product may be used to formulate products for specific use(s) not listed on the Master Product (MP) Label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration for their end-use product(s).

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

- This product is not for formulation into end-use product for use in or on food/feed areas, including food handling establishments (except for crack and crevice, and bait station products) or in/on food/feed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal:

Nonrefillable Containers – Metal: Do not use or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by the State and Local authorities. **Fiber Drums with Liners:** Do not use or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of liner in a sanitary landfill, or by incineration, if allowed by State and Local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

Notice of Warranty and Disclaimer

Seller warrants that at the time of delivery the product in this container conforms to its chemical description contained hereon and is reasonably fit for its intended purpose only when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. This is the only warranty made on this product. To the extent of applicable law seller expressly disclaims any implied warranties of merchantability or fitness for any purpose and, except as set forth above, any other express or implied warranties. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values. It is impossible to eliminate all risks inherently associated with the use of this product. To the extent of applicable law in no case shall Seller be liable for the consequential, special or indirect damages resulting from the use or handling of this product. The Buyer shall assume all such risks. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

